

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Christopher J. Elliott

Serial No.: 10/626,246

Filed: July 24, 2003

For: Embolic Coil

Confirmation No.: 1009

Group Art Unit: 3731

Examiner: Houston, Elizabeth

APPEAL BRIEF-CFR 41.37

M/S: Board of Patent Appeals and Interferences

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

This Appeal Brief is being filed in furtherance of the Notice of Appeal, filed May 24, 2010. It contains the following items in the order indicated below, as required by C.F.R. § 41.37:

- I. Real Party in Interest
- II. Related Appeals and Interferences
- III. Status of Claims
- IV. Status of Amendments
- V. Summary of Claimed Subject Matter
- VI. Grounds of Rejection to be Reviewed on Appeal
- VII. Arguments
- VIII. Claims Appendix
- IX. Evidence Appendix
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I. Real Party in Interest

The real party in interest in this appeal is the assignee, Boston Scientific Scimed, Inc. (formerly, Scimed Life Systems, Inc.), a corporation organized under the laws of Minnesota.

II. Related Appeals and Interferences

There are no appeals or interferences known to the Applicants that will directly affect, would be directly affected by, or would have a bearing on the Board's decision in this appeal.

III. Status of Claims

This application includes pending claims 1, 2, 6-12, 24 and 26-29, all of which stand rejected. Claims 3-5, 13-23 and 25 are cancelled, leaving no claims allowed. The claims on appeal are claims 1, 2, 6-12, 24 and 26-29.

IV. Status of Amendments

All amendments have been entered.

V. Summary of Claimed Subject Matter

Although the claimed subject matter should not be limited to the preferred embodiments described in the specification, the claimed subject matter will now be

described in terms of certain embodiments in order to aid in understanding the claimed subject matter.

Independent claim 1 is directed to an embolic coil 116 to be positioned at a desired location within a blood vessel. See, e.g., ¶ 27 of the specification. As described in ¶ 20 of the specification, the embolic coil 116 comprises an “elongated core element” in the form of a core wire 100 made of a shape memory alloy, such as Nitinol, which is heat treated to thereby give the core wire 100 a secondary coiled configuration 106, as shown in Fig. 5. In this manner, and as described in ¶ 20 of the specification, the core wire 100 is movable between a straightened first configuration when the core wire 100 is stretched out, to a shape memorized coil second configuration 106 when the core wire 100 is no longer being stretched. As described in ¶ 21 of the specification, and shown in Fig. 5c, an “elongated outer element” in the form of a platinum wire 104 is wound around the elongated core wire 100 while the core wire 100 is stretched into its first straightened configuration. As the outer wire 104 is wound around the core wire 100, the outer wire 104 assumes the shape of (and thereby forms) a primary coil 108 having loops or “coils” 108, as shown in Fig. 5d. As described in ¶ 16 of the specification, the embolic coil 116 of claim 1 further comprises a plurality of fibers 22 that are frictionally retained between adjacent coils 108 of the primary coil formed by the wound outer wire 104.

Independent claim 24 is directed to a coiled medical device (e.g., embolic coil 116) for implantation in a patient. See, e.g., specification ¶ 27. As described in ¶ 21 of the specification, the coiled medical device 116 includes a “primary coil” in the form of a platinum wire 104 wound into a helical primary coil shape defining a lumen extending therethrough (See Fig. 5c and Fig. 5d). A “secondary coil” formed of a shape memory alloy core wire 100 is disposed in the lumen, wherein the core wire 100 was previously

heat worked to impart a secondary coil shape 106 (shown in Fig. 5a) before being placed within the lumen of the primary coil (wire 104 wound around wire 100). See specification ¶¶ 20, 21. In this manner, and as explained in specification ¶¶ 22-24, when heated to a temperature above a critical temperature of the shape memory material of core wire 100, the secondary coil (core wire 100) causes the primary coil (platinum wire 104) to follow the secondary coil shape (106 in Fig. 6). As described in ¶ 16 of the specification, the coiled medical device 116 of claim 24 further comprises a plurality of fibers 22 that are frictionally gripped retained between adjacent coils of the primary coil.

Independent claim 27 is directed to an embolic coil (116) comprising an “elongated core element” in the form of a core wire (wire 100 in Fig. 5) formed of a shape memory alloy and treated to define a memorized secondary coil shape 106, as described in specification ¶ 20. As further described in specification ¶ 28, the elongated core wire (wire 120 in Fig. 7; wire 122 in Fig. 8) includes a plurality of fiber retention grooves (cylindrical grooves 124 in Fig. 7; spiral grooves 126 in Fig. 8) formed in an outer surface thereof. As described in specification ¶ 21, an “elongated outer element” in the form of a platinum wire 104 is wound around the elongated core wire 100/120/122 (while the core wire is stretched out as shown in Fig. 5c) to define a primary coil shape (as shown in Fig. 5d) of the embolic coil 116. As described in ¶ 28 read in combination with ¶ 16 of the specification, the embolic coil 116 of claim 27 further comprises a plurality of fibers 22 that are held within the respective fiber retention grooves 124/126.

VI. Grounds of Rejection to be Reviewed on Appeal

A) Whether claims 1, 2, 6-10, 24 and 26 are unpatentable under 35 U.S.C. § 103 (a) as being obvious over U.S. Patent No. 5,980,514 (“Kupiecki”), in view of U.S. Patent No. 5,382,260 (“Dormandy”).

B) Whether claims 11, 12 and 27-29 are unpatentable under 35 U.S.C. § 103 (a) as being obvious over Kupiecki in view of Dormandy, in further view of U.S. Patent No. 6,171,326 (“Ferrera”).

VII. Arguments

Legal standards

The Supreme Court set forth the basic test for obviousness in Graham v. John Deere, 383 U.S. 1, 148 (1966). Additionally, the Supreme Court has addressed the issue of obviousness in KSR International vs. Teleflex Inc., 550 U.S. 398, 127 S. Ct. 1727 (2007), in which the Court reiterated the requirement that a rejection on “obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”, and further that a “fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex parte reasoning”. Further, the Supreme Court in KSR, stated: “A patent composed of several elements is not proven obvious merely by demonstrating that each element was, independently, known in the prior art...it can be important to identified a reason that would have prompted a person of ordinary skill in the relevant field to combined the elements in the way the claimed new invention does.”

Additionally, in Ex parte WHALEN, the BPAI reversed an Examiner’s claim rejections based on obviousness, since the Examiner had not set forth “an adequate basis

– based on evidence or scientific reasoning” to support the rejections. This BPAI cited the Supreme Court decision in KSR, and agreed that “obviousness cannot be proven merely by showing that the elements of a claimed device were known in the prior art; it must be shown that those of ordinary skill in the art would have had some ‘apparent reason to combine the known elements in the fashion claimed’ (Ex parte Whalen, citing KSR at 1741).

While not specifically addressed by the Supreme Court in KSR, for a combination of prior art references to render a claimed device obvious, a device resulting from the combination of prior art references must still consider **all** of the limitations of that claim (See MPEP § 2143). Also, a “prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” MPEP § 2141.03 (VI). “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious.” MPEP § 2143.02 (VI).

The above analyses should be applied to determine whether or not the cited references render the appealed claims obvious. For the reasons that follow, Appellants respectfully submit the appealed claims are not obvious in view of the cited references.

A) Rejection of claims 1, 2, 6-10, 24 and 26 under 35 U.S.C. §103(a) over Kupiecki in view of Dormandy

Independent claim 1 recites an embolic coil comprising “an elongated core element formed of a shape memory material and movable between a straightened first configuration and a shape memorized second coiled configuration; an elongated outer

element which, in the first configuration, is wound around the elongated core element to form a primary coil; and *a plurality of fibers frictionally gripped between adjacent coils of the primary coil.*” (Emphasis added). Claims 2 and 6-10 depend from claim 1, and thus include these same limitations. Independent claim 24 similarly recites a coiled medical device comprising a primary coil having a primary coil shape, and a secondary coil formed of a shape memory material and disposed in a lumen extending through the primary coil, the secondary coil having a secondary coil memorized shape, the device further comprising “*a plurality of fibers gripped between adjacent coils of the primary coil and held therebetween by friction.*” (Emphasis added). Claim 26 depends from claim 24, and thus includes these same limitations.

An explanation of the claimed frictional fiber retention aspects of the devices of claims 1 and 24 is set forth in paragraphs 16 and 17 of the specification:

[0016] FIG. 4 shows an exemplary embodiment of fibers 22 being attached to the primary coil 54 of an embolic coil. As indicated above, the fibers 22 may be polymeric fibers or may be made of other flexible materials, for example, Nitinol. The fibers 22 are added to the platinum primary coil 54 to impart greater thrombogenicity to the overall embolic coil, and to increase its ability to stop the undesired flow of blood therethrough. **The fibers 22 are generally inserted between the loops 56 of the primary coil 54, and are held in place by virtue of the cold work imparted to the platinum wire during the primary coil winding process.** In an exemplary embodiment, the insertion of the fibers 22 in the loops 56 is carried out after the heat treatment used to set and maintain the shape of the secondary coil 62.

[0017] However, other processes may be better suited to forming embolic coils having enhanced shape retention and fiber retention properties. **Specifically, the retention of the fibers 22 between the loops 56 of the primary coil 54 is a**

function of the amount of cold work that has been performed and that continues to affect the platinum wire 50. In other words, the fibers 22 remain in place more securely when a large amount of cold work is performed that is not later removed. ***

(Emphasis added).

The Examiner has correctly stated that Kupiecki does not teach or suggest the attachment of fibers to the coil device by any means, and cites Dormandy in support of the rejection. (Final Office Action mailed February 24, 2010, ¶4 on page 3).

However, Appellant respectfully submits that Dormandy does not teach that the fibers are “frictionally gripped between adjacent coils of the primary coil,” as recited in claim 1, or “gripped between adjacent coils of the primary coil and held therebetween by friction,” as recited in claim 24, but instead that the fibers (22) are wound around turns of the coil, and held in place by a loop (23) formed by the winding. (See Dormandy, col. 3, lines 50-60, “loop 23 serves as the sole means for retaining the group 21 of fibers 22 on the coil 12.”). This is clearly shown in Figs. 3 and 4 of Dormandy:

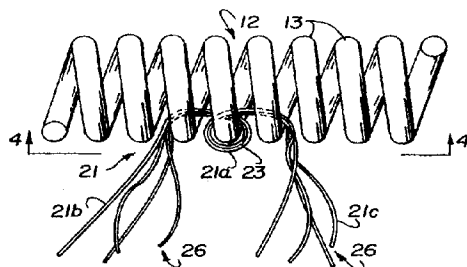


FIG. 3

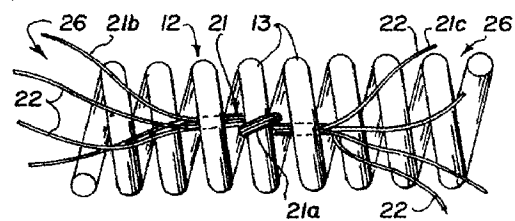


FIG. 4

It is respectfully submitted that the fibers (22) of Dormandy are not frictionally gripped between adjacent coils of the coil (12), especially in light of the fact that adjacent turns of the coil (12) are shown to be spaced from one another. Nor does Dormandy teach or suggest that adjacent turns of the coil (12) are wound tightly against one another.

Moreover, the modification of Kupiecki proposed by the Examiner (See Final Office Action mailed February 24, 2010, ¶4 on page 3) provides unexpected results.

In particular, Dormandy teaches fibers (22) that are wound around turns of the coil (12) to form a loop (23) by inserting a first free end of the fiber (22) between two turns of a coil and into a cavity located within the coil (12) and the free end is then looped around a turn of the coil and inserted back into the cavity before being drawn out of the coil (12) one last time. It is unclear how incorporating the fibers (22) of Dormandy into the coil device of Kupiecki would result in the device of independent claims 1 or 24, since the fibers (22) of Dormandy cannot be looped around the wire (202) of Kupiecki due to obstruction by the inner core member (204). (*See* Kupiecki, col. 14, ll. 3 - 45; Fig.8).

In order to achieve the desired helical shape, to the wire (202) of Kupiecki must be wound in a tight configuration over the inner core member (204) as a loose winding is incapable of imparting the desired coiled shape. However, Kupiecki states that the wire (202) is secured to the outer body of the inner core member (204) by welding the contacting ends thereof together, thus confirming that the wire (202) is wound tightly over the inner core member (204) so that the resulting coil is held in a contacting configuration therewith. (*Id.* at col. 14, ll. 26 - 32). Thus, the modification proposed by the Examiner would not result in the claimed invention, and it is respectfully submitted that neither Kupiecki nor Dormandy, taken either alone or in combination, disclose or suggest an embolic coil comprising a plurality of fibers that are “frictionally gripped between adjacent coils of the primary coil,” as recited in claim 1, or “gripped between adjacent coils of the primary coil and held therebetween by friction,” as recited in claim 24.

For at least these reasons, Appellant respectfully submits that the Examiner has not set forth a prima facie case that claims 1, 2, 6-10, 24 and 26 are unpatentable under 35 U.S.C. § 103 (a), as being obvious over Kupiecki in view of Dormandy.

B) Rejection of claims 11, 12 and 27-29 under 35 U.S.C. §103(a) over Kupiecki in view of Dormandy, in further view of Ferrera

Claims 11-12

Claims 11 and 12 depend from claim 1, and thus also include the limitation of a plurality of fibers that are “frictionally gripped between adjacent coils of the primary coil.” As explained above, the combination of Kupiecki in view of Dormandy does not teach this limitation under 35 U.S.C. § 103 (a).

Nor does Ferrera disclose or suggest an embolic coil having a plurality of fibers that are “frictionally gripped between adjacent coils of the primary coil.” Nor has the Examiner contended that Ferrera provides this key teaching that is missing from Kupiecki and Dormandy. Instead, Ferrera was cited for the teaching of an elongated outer element comprising a platinum wire co-wound with a shape memory material (as required by claim 12).

Thus, for at least the same reasons discussed above with respect to independent claim 1, Appellant respectfully submits that the Examiner has not set forth a prima facie case that claims 11 and 12 are unpatentable under 35 U.S.C. § 103 (a), as being obvious over Kupiecki in view of Dormandy, and in further view of Ferrera.

Claims 27-29

Independent claim 27 recites an embolic coil comprising “an elongated core element formed of a shape memory material treated to define a memorized secondary coil shape, the elongated core including a plurality of fiber retention grooves formed in an outer surface thereof; an elongated outer element wound around the elongated core element to define a primary coil shape of the embolic coil; and a *plurality of fibers held within the first fiber retention grooves.*” (Emphasis added). Claims 28 and 29 depend from claim 27, and thus includes these same limitations.

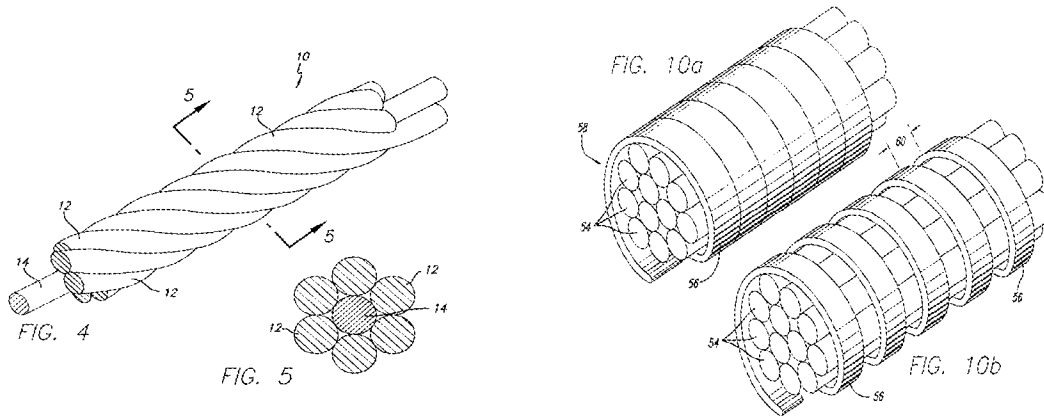
An explanation of the claimed frictional fiber retention aspects of the device of claim 27 is set forth in paragraph 28 of the specification (with reference to Figs. 7 and 8):

[0028] Additional enhancements may be made to the embolic coil according to the present invention, to improve the device's fiber retention properties. **For example, as shown in FIG. 7, the shape memory core wire 120 may comprise cylindrical grooves 124 that are used as anchors for fibers. Grooves 124 channel the fiber bundles around core wire 120, so that they are held in place by the core wire 120.** In this manner the primary coil 108 is freed from that function. Channeling the fiber bundles via grooves 124 promotes cohesion of the fibers, and reduced the loss of fibers during use of the embolic coil. **In a different embodiment shown in FIG. 8, a shape memory core wire 122 may comprise spiral grooves 126, which also help anchor fibers such as the fibers 22 shown in FIG. 4.** In these embodiments, the amount of cold work imparted to the primary coil 108 has less effect on how well the fibers 22 are retained, and fewer restrictions are imposed on the shape and properties of the primary coil 108. (Emphasis added).

Appellant respectfully submits that Ferrera does not disclose or suggest an embolic coil comprising “an elongated core element formed of a shape memory material treated to define a memorized secondary coil shape, the elongated core including *a plurality of fiber retention grooves formed in an outer surface thereof*; an elongated

outer element wound around the elongated core element to define a primary coil shape of the embolic coil; and a *plurality of fibers held within the first fiber retention grooves.*” (Emphasis added).

The Examiner states that “the resultant combination of Ferrera’s multi-stranded cable with the base [Kupiecki] device provides fiber retention grooves as claimed (Note the circumferential and spiral grooves formed between each strand in Fig. 4, as well as the circumferential and spiral groove formed by the wrapped cover (56) in Figs. 10a and 10b).” (Final Office Action mailed February 24, 2010, ¶9 on page 4). However, it can be plainly seen in the referenced figures of Ferrera that the spaces between the cables do not comprise a plurality of fiber retention grooves formed in an outer surface of an elongated core element, as required by independent claim 27:



For at least these reasons, Appellant respectfully submits that the Examiner has not set forth a prima facie case that claims 27-29 are unpatentable under 35 U.S.C. § 103 (a), as being obvious over Kupiecki in view of Dormandy, in further view of Ferrera.

Respectfully submitted,

VISTA IP LAW GROUP LLP

Dated: September 7, 2010

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VIII. Claims Appendix

1. An embolic coil comprising:

an elongated core element formed of a shape memory material and movable between a straightened first configuration and a shape memorized second coiled configuration;

an elongated outer element which, in the first configuration, is wound around the elongated core element to form a primary coil; and

a plurality of fibers frictionally gripped between adjacent coils of the primary coil.
2. The embolic coil according to claim 1, wherein the shape memory material is formed at an operational temperature of the embolic coil in an austenitic phase.
6. The embolic coil according to claim 1, wherein the memorized shape of the elongated core element is substantially a coil.
7. The embolic coil according to claim 1, wherein the memorized shape of the elongated core element is substantially a three dimensional spiral.
8. The embolic coil according to claim 1, wherein the shape memory material of which the elongated core element is formed includes Nitinol.
9. The embolic coil according to claim 1, wherein the elongated outer element is formed of platinum.

10. The embolic coil according to claim 1, wherein the primary coil shape is a substantially cylindrical coil.
11. The embolic coil according to claim 1, further comprising a plurality of fiber retention grooves formed on the elongated core element.
12. The embolic coil according to claim 1, wherein the elongated outer element comprises a platinum wire co-wound with a wire formed of a shape memory material.
24. A coiled medical device for implantation in a patient comprising:
 - a primary coil having a primary coil shape, the primary coil defining a lumen extending therethrough;
 - a secondary coil formed of a shape memory material and disposed in the lumen, the secondary coil having a secondary coil memorized shape, wherein, when heated to a temperature above a critical temperature of the shape memory material, the secondary coil causes the primary coil to follow the secondary coil shape; and
 - a plurality of fibers gripped between adjacent coils of the primary coil and held therebetween by friction.
26. The medical device according to claim 24, wherein the shape memory material includes Nitinol.
27. An embolic coil comprising:

an elongated core element formed of a shape memory material treated to define a memorized secondary coil shape, the elongated core including a plurality of fiber retention grooves formed in an outer surface thereof;

an elongated outer element wound around the elongated core element to define a primary coil shape of the embolic coil; and

a plurality of fibers held within the first fiber retention grooves.

28. The embolic coil of claim 27, wherein the fiber retention grooves extend circumferentially about the elongated core element.

29. The embolic coil of claim 27, wherein the fiber retention grooves extend about the elongated core element along a spiral path.

IX. Evidence Appendix

A. U.S. Patent No. 5,980,514, which was originally cited by the Examiner in the Office Action mailed September 5, 2006.

B. U.S. Patent No. 5,382,260, which was originally cited by the Examiner in the Notice of References Cited attached to the Office Action mailed April 25, 2007.

C. U.S. Patent No. 6,171,326, which was originally cited by the Examiner in the Office Action, dated September 5, 2006.

X. Related Proceedings Appendix

None.